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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,125	07/08/2003	Axel Grandt	JM-040	2218

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07/05/2006

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,125

Applicant(s)

GRANDT, AXEL

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 9, 10, 13, 14, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-8, 11, 12, 15-18 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/7/06 has been entered.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the written disclosure failed to describe the tubular member as having a "substantially continuous internal lumen of uniform cross-section..". Thus the prior art will be interpreted with Applicant's undefined limitation as best understood.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,5-8,11,12,23 are rejected under 35 U.S.C. 102(b) as being anticipated by Yan (5843172). Fig. 2 shows a stent **20** formed of a tubular member with a lumen therein and a multiplicity of pores **18** in fluid communication with the lumen and the pores are circumferentially about an exterior surface and spaced at variable distances

with respect to one another since they are randomly dispersed on the stent. The use of "substantially continuous internal lumen" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited.

Thus the interpretation of the prior art is taken with its broadest reasonable interpretation. Since the entire stent is coated with the polymer solution and then implanted, it is inherent the inner surface is covered with the agent and is disposed within the lumen of the stent and is then eluted upon degradation of the polymer, col. 5, lines 39-41,47-50. Yan also discloses a therapeutic agent is within a bioabsorbable polymer (col. 5, lines 1-6,30,31, col. 9, lines 16-19). Fig. 1 shows a stent with a plurality of upper peaks and lower peaks forming a ring. Please note the method of making the rings carries no weight, since product claims are not limited to how they are produced.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Globerman et al. (WO 96/26682) in view of Brown et al. (6071305). Fig. 5 shows a coiled stent **12** formed of a tubular member **14** with a lumen **16** therein. Globerman discloses the stent can have a multiplicity of pores in fluid communication with the lumen (page 7, lines 11-15) for a therapeutic agent disposed within the lumen to be eluted from the stent. The use of "substantially continuous internal lumen" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered

Art Unit: 3738

broad and relatively unlimited. Thus the interpretation of the prior art is taken with its broadest reasonable interpretation. Globerman also discloses the stent tubular member can be made of shape memory material, page 7, lines 9-10. However, Globerman fails to disclose the use of a bioabsorbable polymer to elute the therapeutic agent. Brown teaches that bioabsorbable polymers (col. 8, lines 62-65, col. 9, line 1) are used as means for controlling release into the lumen of the patient. It would have been obvious to one of ordinary skill in the art to use a bioabsorbable polymer with a therapeutic agent to deliver a therapeutic agent as taught by Brown with the stent of Globerman in order to provide a means to control the rate of delivery of the drug.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Globerman et al. '682 in view of Leone et al. (5882335). Globerman is explained supra. However, Globerman fails to disclose the pores are disposed circumferentially about an exterior surface of the tube. Leone shows (Fig. 5) a coil shape with the pores disposed circumferentially about the exterior surface of the tubular member. It would have been obvious to one of ordinary skill in the art to use circumferentially disposed pores as taught by Leone in the stent of Globerman such that therapeutic material can be evenly distributed within the vessel.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Globerman et al. '682. Globerman is explained supra. However, Globerman fails to disclose the pores spaced at variable distances with respect to one another. It would have been an obvious matter of design choice to modify the location of the pores, since applicant has not disclosed that using variable distance locations between the pores

provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the pore locations taught by Globerman or the claimed variable distance located pores in claim(s) 22 because both stents perform the same function of releasing therapeutic material through pores.

Claims 15,18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tower et al. (EP 1057460) in view of Globerman et al. (WO 96/26682) and Brown et al. '305. The use of "substantially continuous internal lumen" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. Thus the interpretation of the prior art is taken with its broadest reasonable interpretation. Tower discloses (Fig. 2) a plurality of rings affixed together to form the stent. Tower also discloses that the rings are formed from wire shaped into sinusoidal bends, col. 4, lines 55-58 and col. 5, lines 33-39. However, Tower fails to disclose the tubular members having pores and a lumen with therapeutic material therein. Drug eluting stents are well known in the art. Globerman is explained supra. Brown is explained supra. It would have been obvious to one of ordinary skill in the art to form the stent rings with a lumen to hold pharmaceutical material as taught by Globerman and use a biodegradable polymer as taught by Brown with the stent of Tower et al. to provide a controlled delivery therapeutic stent.

Response to Arguments

Applicant's arguments filed 4/7/06 have been fully considered but they are not persuasive. In response to applicant's argument that Yan fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., use of a solid wall tube) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant also argues that Brown does not suggest the bioabsorbable polymer controls the rate of elution of the therapeutic agent. It should be noted that it is irrelevant whether or not the polymer controls the rate of the delivery of the agent since the claimed limitations are met. However, in order to address the remarks it is noted that Brown states that the polymer does play a role in controlling delivery of the agent, see col. 9, lines 7-9. This implies a highly soluble agent is combined with a polymer that would slow or control the delivery in the patient such that it does not release more than the patient can absorb. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 6:30am to 4pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4756. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

A handwritten signature in black ink that reads "Brian E. Pellegrino". The signature is written in a cursive, flowing style.